UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---------------------------------|---|----------------------|---------------------|------------------|--|
| 10/567,131 | 02/07/2006 | Chava Satyanarayana | 0288035PJAB | 8791 | |
| | 22831 7590 11/06/2008 SCHWEITZER CORNMAN GROSS & BONDELL LLP | | | EXAMINER | |
| 292 MADISON AVENUE - 19th FLOOR | | | CHANG, CELIA C | | |
| NEW YORK, N | NEW YORK, NY 10017 | | ART UNIT | PAPER NUMBER | |
| | | | 1625 | | |
| | | | | | |
| | | | MAIL DATE | DELIVERY MODE | |
| | | | 11/06/2008 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|
| | 10/567,131 | SATYANARAYANA ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Celia Chang | 1625 | | | | |
| The MAILING DATE of this communication ap Period for Reply | pears on the cover sheet with the c | correspondence address | | | | |
| · · | VIC OFT TO EVOIDE 4 MONTH | (C) OD TUUDTY (20) DAYC | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | NATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tirwill apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>05 J</u> | une 2006. | | | | | |
| | s action is non-final. | | | | | |
| 3) Since this application is in condition for allowa | | | | | | |
| closed in accordance with the practice under | Ex parte Quayle, 1935 C.D. 11, 4 | 53 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-19</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8)⊠ Claim(s) <u>1-19</u> are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | er. | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the E | xaminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreigr | n priority under 35 U.S.C. § 119(a |)-(d) or (f). | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | | |
| 1.⊠ Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Burea | | | | | | |
| * See the attached detailed Office action for a list | of the certified copies not receive | ed. | | | | |
| | | | | | | |
| Attachment(s) | _ | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) | 5) 🔲 Notice of Informal F | | | | | |
| Paper No(s)/Mail Date <u>6/5/06</u> . | 6) | | | | | |

Application/Control Number: 10/567,131 Page 2

Art Unit: 1625

DETAILED ACTION

1. This application is a 371 of PCT/IN2004/000233.

A preliminary amendment was filed on Feb. 7 2006.

Claims 1-19 are pending.

2. Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-6, drawn to crystalline moxifloxacin hydrochloride monohydrate and process of making, classified in class 514, subclass 300.
- II. Claims 7-19, drawn to quinoline carboxylic acid-O,O bis-acyloxyborate and process of making, classified in class 546, subclass .

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as material for making other products such as found in US 5,157,117 (recited on 1449) and the inventions are deemed patentably distinct because there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above <u>and</u> there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

Application/Control Number: 10/567,131

Art Unit: 1625

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

Page 3

- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 10/567,131 Page 4

Art Unit: 1625

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang Oct. 29, 2008

/Celia Chang/ Primary Examiner Art Unit 1625